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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/565,023

07/18/2006

Esa Suokas

12808/29

9012

26646

7590

12/08/2009

KENYON & KENYON LLP
ONE BROADWAY
NEW YORK, NY 10004

EXAMINER

HORNBERGER, JENNIFER LEA

ART UNIT

PAPER NUMBER

3734

MAIL DATE

DELIVERY MODE

12/08/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/565,023	Applicant(s) SUOKAS ET AL.	
	Examiner JENNIFER L. HORNBERGER	Art Unit 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 September 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 and 28-31 is/are pending in the application.
- 4a) Of the above claim(s) 28-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26 and 31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Claims 1-26 and 28-31 are pending. Claims 28-30 are currently withdrawn.

Response to Amendment

2. The declaration under 37 CFR 1.132 filed 09/14/2009 is insufficient to overcome the rejection of claims 1-26 and 31 based upon Tormala et al. (US 6,406,498) as set forth in the last Office action because: Applicant argues that Tormala et al. refer antibiotics and other general without mentioning any specific properties of these agents, such as melting temperature. However, bioactive glass is inherently antibacterial as evidenced by Tormala et al. in col. 7, ln. 57-65 of US Patent No. 6,579,533. Furthermore, the bioactive glass maintains its solid form during melt processing of the matrix.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-4 and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Törmälä et al. (US 6,406,498).

Regarding claim 1, Törmälä et al. disclose a multifunctional synthetic bioabsorbable device, comprising: a synthetic bioabsorbable oriented polymeric matrix (col. 3, ln. 5-9); solid particles of a pharmacological agent (col. 3, ln. 10-11) selected from the group consisting of an antibiotic, an antibacterial agent, and an anti-inflammatory agent, cavities induced around the solid particles of the pharmacological agent dispersed in said synthetic bioabsorbable oriented

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polymeric matrix, wherein the pharmacological agent is capable of retaining its solid particulate form in the melt processing temperature of the matrix (col. 7, ln. 44-50).

Regarding claim 2, Törmälä et al. disclose the claimed invention spindle-shaped or oval-shaped cavities (Fig. 8B). Since said cavities cause reduced Young's modulus and increased elasticity, it would be reasonable to expect that the device of Törmälä et al. having cavities would have the same properties.

Regarding claim 3, Törmälä et al. disclose the device is a suture, fiber, thread, cord, or wire (col. 6, ln. 5-6).

Regarding claim 4, Törmälä et al. disclose the device is a mesh (col. 6, ln. 5-6).

Regarding claim 31, Törmälä et al. disclose the synthetic bioabsorbable oriented polymeric matrix is of poly- α -hydroxy acid polymer (col. 4, ln. 19).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-26 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischer et al (EP 1157708) in view of Törmälä et al. (US 6,406,498).

Regarding claim 1, Fischer et al. disclose a multifunctional synthetic bioabsorbable device comprising: a synthetic bioabsorbable polymeric matrix, particles of a pharmacological agent (paragraph 7). Fischer et al. fail to disclose an oriented polymeric matrix having cavities induced around the particles of the pharmacological agent dispersed in said synthetic bioabsorbable polymeric matrix. However, Törmälä et al. disclose a synthetic bioabsorbable

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oriented polymeric matrix (col. 4, ln. 16-17) having cavities encapsulating solid bioactive glass or ceramic particles (col. 3, ln. 5-20, col. 7, ln. 44-50). The bioactive glass/ceramic is capable of retaining its solid particulate form in the melt processing temperature of the matrix (col. 7, ln. 44-50). Törmälä et al. discloses that applying orientating and or self-reinforcing techniques to bioabsorbable polymeric composites that include bioactive absorbable ceramic filler creates strong, tough, bioactive polymer composites which are useful in meshes, fibers, and threads (col. 5, ln. 53 - col. 6, ln. 10). Therefore, it would have been obvious to one of ordinary skill in the art to apply orienting and self-reinforcing techniques to the polymer composite of Fischer et al. and to provide an antibacterial pharmacological agent in the form of bioactive glass or ceramics in order to provide increased strength as suggested by Törmälä et al. It follows that applying the techniques of Törmälä et al. would induce cavities around the bioactive glass/ceramic in the device of Fischer et al.

Regarding claim 2, Fischer et al. in view of Törmälä et al. disclose the claimed invention spindle-shaped or oval-shaped cavities (Fig. 8B). Further, since said cavities cause reduced Young's modulus and increased elasticity, it would be reasonable to expect that the device of Fisher et al. in view of Törmälä et al. also having cavities would have the same properties.

Regarding claim 3, Fischer et al. disclose the device is a suture, fiber, thread, cord, or wire (paragraph 7).

Regarding claims 4 and 5, Fischer et al. disclose the device is a mesh (paragraph 18) comprising fibers of differing bioabsorbable properties (paragraph 10).

Regarding claim 6, Fischer et al. disclose the mesh comprises bioabsorbable fibers and non-bioabsorbable fibers, or fibers of differing bioabsorption rates (paragraph 10).

Regarding claims 7-9, Fischer et al. disclose the pharmacological agent is an antibiotic in that it inhibits bacterial growth (paragraph 7).

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Regarding claims 10-12, Fischer et al. disclose the pharmacological agent comprises 0.01 to 50 wt-% of the weight of the said multifunctional device (paragraph 16).

Regarding claims 13-15, Fischer et al. discloses the claimed invention except for said pharmacological agent comprises 1-10 wt-% of the weight of the said multifunctional device. It would have been obvious to one having ordinary skill in the art at the time the invention was made to ascertain the effective minimum and maximum amounts of the pharmacological agent, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Regarding claims 16-18, Fischer et al. discloses the said multifunctional device is monofilamentous in its structure (paragraph 7, ln 41).

Regarding claims 19-21, Fischer et al. discloses the said multifunctional device is multifilamentous in its structure (paragraph 10).

Regarding claims 22-24, Fischer et al. disclose the said multifunctional device has a drug releasing function effective to inhibit bacterial attachment and biofilm formation (paragraph 7, line 43).

Regarding claim 25, Fischer et al. discloses it is made by melt or solution processing technique and subsequent processing method (paragraph 15).

Regarding claim 26, Fischer et al. discloses the subsequent processing method is fiber spinning (paragraph 15).

Regarding claim 31, Fischer et al. fails to disclose poly- α -hydroxy acid polymer. Törmälä et al. disclose poly- α -hydroxy acid polymers are suitable for forming the bioabsorbable polymeric matrix. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use poly- α -hydroxy acid polymers to form a bioabsorbable polymeric

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matrix, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Response to Arguments

7. Applicant's arguments filed 09/14/2009 have been fully considered but they are not persuasive. Applicant argues that Tormala et al. fail to disclose a pharmaceutical agent capable of retaining its solid particulate form in the melt-processing temperature. Examiner respectfully disagrees. Tormala et al. disclose a synthetic bioabsorbable oriented polymeric matrix (col. 4, ln. 16-17) having cavities encapsulating solid bioactive glass or ceramic particles (col. 3, ln. 5-47, col. 7, ln. 44-50). The bioactive glass maintains its solid form at the melt processing temperature. The bioactive glass is inherently antibacterial as evidenced by Tormala et al. in col. 7, ln. 57-65 of US Patent No. 6,579,533.

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER L. HORNBERGER whose telephone number is (571)270-3642. The examiner can normally be reached on Monday through Friday from 8am-5pm, Eastern time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571)272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

jlh
12/03/2009

/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3734